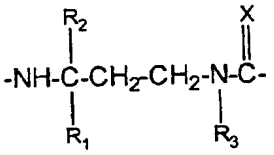
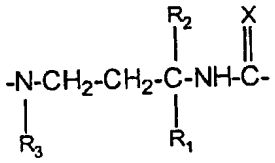
REMARKS

Claims 1-18 are pending in this application. Claims 1-11 and 18 are currently being examined, and claims 12-17 are withdrawn from consideration. By this Amendment, claim 1 is amended to address formal matters. No new matter is added.

I. Restriction Requirement

Applicants affirm election of Group I, claims 1-11 and 18, with traverse. Applicants respectfully assert that all of claims 1-18 share a special technical feature, and thus should be examined together under 35 U.S.C. §371. Specifically, claim 1 recites the special technical feature:

> at least one unit chosen from the B units of general formulae (I) and/or (II):
>
> 
> (I)
>
> 
> (II)
>
> in which: R_1, R_2 and R_3 each independently of one another represent an amino acids side chain and may be identical or different, and X represents an oxygen or sulfur atom.

All of claims 2-18 ultimately depend from claim 1, and include this special technical feature. Accordingly, under §371, claims 12-17 should be rejoined to, and examined with, claims 1-11 and 18. See MPEP §1893.03(d).

II. Written Description Rejection

The Office Action rejects claims 1-11 and 18 under the written description requirement of 35 U.S.C. §112, first paragraph. Applicants respectfully traverse the rejection.

In order to satisfy the written description requirement of §112, first paragraph, the patent specification must describe the claimed invention in sufficient detail that one skilled in

the art can reasonably conclude that the inventor had possession of the claimed invention. See MPEP §2163. Possession may be shown in structural chemical formulae that permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. See MPEP §2163, citing (Vas-Cath).

Claims 1-4 are directed to pseudopeptides, of at least 6 amino acids, at least 9 amino acids, or at least 12 amino acids, comprising at least one unit chosen from the B units of the structural chemical formulae (I) and (II). Claims 5-7 are directed to a method of making the pseudopeptide of claim 1, claims 8-11 are directed to a reagent or kit comprising at least one pseudopeptide according to claim 1, and claim 18 is directed to an active therapeutic composition comprising at least one pseudopeptide according to claim 1. The specification, in view of that which is well known in the art, describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that Applicants had possession of the claimed invention.

Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information that is well known in the art need not be described in detail in the specification. The description need only describe in detail that which is new or not conventional. See MPEP §2163 (citing Hybritech, Inc. v. Monoclonal Antibodies, Inc.).

As disclosed in the specification, pseudopeptides are well known in the art, and may be peptide analogs of epitopes. See page 1, lines 4-13 and page 2, lines 5-9. These conventional pseudopeptides may include, for example, known compounds having bonds that mimic peptide bonds. See page 1, line 1 to page 2, line 3. It is also well known in the art that epitopes tend to have a size of from a few amino acids to about 15 to about 22 amino acids, and that the peptide analogs of these epitopes are synthesized to be approximately the same size as the corresponding epitope. See page 2, lines 16-18.

For example, it is known in the art that epitopes to the MHC class I molecules are 9-13 amino acids in size, and epitopes to the MHC class II are 9-25 amino acids in size. See page 2, lines 18-23. In addition, it is well known in the art that epitopes for HIV diagnosis are 4-6 amino acids in size. See page 2, lines 26-28. Furthermore, it is well known in the art how to make these conventional pseudopeptides, of various sizes ranging from about 4 amino acids to about 25 amino acids. See page 5, lines 1-37, and page 6, line 34 to page 7, line 3.

In addition, as disclosed in the specification, it is well known in the art to use these conventional pseudopeptides in active therapeutic compositions, such as vaccines. See page 11, lines 24-33. It is well known that peptide analogs may advantageously replace natural peptides in therapeutic treatments. See page 13, lines 5-16. For example, it is known in the art that the modifications of the peptide backbone can considerably influence the interactions of the MHC complex/peptide with the receptor for the T lymphocytes in therapeutic treatments. See page 13, lines 16-29. Furthermore, as disclosed in the specification, it is well known in the art to use these conventional pseudopeptides in reagents and kits for detecting a pathological condition. See page 6, lines 1-9. For example, it is well known that pseudopeptides can be labeled with biotin in order to serves as reagents for detecting biological molecules. See page 6, lines 11-13.

In summary, pseudopeptides of at least 6 amino acids (and at least 9 amino acids and at least 12 amino acids) having compounds with bonds that mimic peptide bonds are well known in the art. Furthermore, it is well known in the art to use these conventional pseudopeptides in active therapeutic compositions, and reagents and kits for detecting a pathological condition. In view of MPEP §2163 and Hybritech, Inc. v. Monoclonal Antibodies, Inc., the specification need only describe in detail that which is new or not conventional in order to satisfy the written description requirement of §112, first paragraph.

Thus, in order to satisfy the written description requirement of §112, first paragraph, the specification need only describe the claimed compounds of the general forumulae (I) or (II).

As stated by MPEP §2163 and Vas-Cath, possession of the claimed invention may be shown by structural chemical formulae. The specification describes the Applicants' claimed compounds in great detail, including the structural chemical formulae, so as to permit a person skilled in the art to clearly recognize that applicant had possession of the claimed compounds under MPEP §2163 and Vas-Cath. See general formulae (I) and (II), and page 3, line 1 to page 4, line 26. In addition, although it is well known in the art how to make pseudopeptides having compounds with bonds that mimic peptide bonds, the specification also describes how to make the claimed pseudopeptides. See, for example, page 5, lines 16-37.

Because pseudopeptides of at least 6 amino acids (and at least 9 amino acids and at least 12 amino acids) having compounds with bonds that mimic peptide bonds are well known in the art, and because the specification describes the Applicants' claimed compounds in great detail so as to permit a person skilled in the art to clearly recognize that applicant had possession of the claimed compounds, one skilled in the art can reasonably conclude that applicants had possession of the claimed pseudopeptides of at least 6 amino acids, (and at least 9 amino acids and at least 12 amino acids) that include at least one unit chosen from the B units of the structural chemical formulae (I) and (II). Furthermore, because it is well known in the art that pseudopeptides can be used in therapeutic compounds, or in reagents and kits, one skilled in the art can also reasonably conclude that applicants had possession of the claimed reagent, kit and active therapeutic at the time the application was filed.

For at least these reasons, the specification describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that Applicants had possession of the claimed invention at the time the application was filed. Accordingly, claims

1-11 and 18 satisfy the written description requirement of §112, first paragraph. Reconsideration and withdrawal of the rejection are respectfully requested.

III. Enablement Rejection

The Office Action rejects claims 1-11 and 18 under the enablement requirement of 35 U.S.C. §112, first paragraph. Applicants respectfully traverse the rejection.

Claims 1-4 are directed to pseudopeptides, of at least 6 amino acids, at least 9 amino acids, or at least 12 amino acids, comprising at least one unit chosen from the B units of the structural chemical formulae (I) and (II). Claims 5-7 are directed to a method of making the pseudopeptide of claim 1, claims 8-11 are directed to a reagent or kit comprising at least one pseudopeptide according to claim 1, and claim 18 is directed to an active therapeutic composition comprising at least one pseudopeptide according to claim 1. One of ordinary skill in the art could make or use the claimed invention, based on what is known in the art and described in the specification, without undue experimentation.

The test for enablement is whether one of ordinary skill in the art could make or use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation. See MPEP §2164.01. All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. See MPEP §2164.08 (citing In re Fisher). Nevertheless, not everything necessary to practice the claimed invention need be disclosed. In fact, what is well-known is best omitted. See MPEP §2164.08 (citing In re Buchner).

As disclosed in the specification, pseudopeptides are well known in the art, and may be peptide analogs of epitopes that include known compounds having bonds that mimic peptide bonds. See page 1, line 1 to page 2, line 9. It is also well known in the art that the peptide analogs are synthesized to be approximately the same size as the corresponding epitope, e.g., various sizes ranging from about 4 amino acids to about 25 amino acids. See

page 2, lines 16-23, page 5, lines 1-37, and page 6, line 34 to page 7, line 3. In addition, it is well known in the art to use these conventional pseudopeptides in active therapeutic compositions, such as vaccines. See page 11, lines 24-33 and page 13, lines 5-16. Furthermore, it is well known in the art to use these conventional pseudopeptides in reagents and kits for detecting a pathological condition. See page 6, lines 1-13.

In view of MPEP §2164.08 and In re Buchner, the specification need only enable that which is not well-known in the art in order to satisfy the enablement requirement of §112, first paragraph. MPEP §2164.02 states that compliance with the enablement requirement of does not turn on whether an example is disclosed. Thus, in order to satisfy the enablement requirement of §112, first paragraph, the specification need only describe the claimed compounds of the general forumulae (I) or (II) in sufficient detail to allow one skilled in the art to make and use claimed compounds and pseudopeptides.

Specifically, the specification discloses the chemical structural formulae (I) and (II) for the claimed compounds. See page 3, lines 1-20. The specification defines, in great details, each of R_1, R_2, R_3 and X. See page 3, line 20 to page 4, line 12. Furthermore, the specification further describes the chemical structures (I) and (II) by stating that "[p]referably, the NH functional group of formula I and the NR_3 functional group of formula II are linked to a group CX, and/or the CX functional group of formulae I and II are linked to a group NH or NR_3, said groups CX, NH and NR_3 belonging to a peptide or pseudopeptide unit." See page 4, lines 21-26.

When examples are provided in patent specifications, the examples may be "working" or "prophetic." Prophetic examples are examples that describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved. See MPEP 2164.02. Although examples are not required to satisfy the enablement requirement, and although it is well known in the art how to make pseudopeptides having

compounds with bonds that mimic peptide bonds, the specification describes how to make the claimed pseudopeptides. See, for example, page 4, line 28 to page 5, line 37. Furthermore, the specification describes specific modifications that can be made to the psuedopeptides when used in therapeutic compositions, reagents and kits. See, for example, page 6, line 1 to page 7, line 3. In addition, the specification provides three working examples, describing how to make and use the claimed compounds and pseudopeptides.

MPEP §2164.01(b) states that as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. Furthermore, MPEP §2164.01(c) states that if a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, 35 U.S.C. 112 is satisfied.

As discussed above, the specification, in view of what is well known in the art, discloses at least one method for making and using the claimed compounds and pseudopeptide that bears a reasonable correlation to the entire scope of the claims. Furthermore, the specification, in view of what is well known in the art, discloses how to make and use the claimed compounds, and the art recognizes that standard modes of making and using pseudopeptides are known and contemplated. In addition, the specification, in view of what is well known in the art, describes the claimed compounds and pseudopeptides such that one skilled in the art would be able to make and use the claimed invention without undue experimentation, and the specification even describes both working and prophetic examples of the claimed invention.

For at least these reasons, one reasonably skilled in the art could make or use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation. Accordingly, claims 1-11 and 18 satisfy the

enablement requirement of §112, first paragraph. Reconsideration and withdrawal of the rejection are respectfully requested.

IV. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1-18 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

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WPB:PAC

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